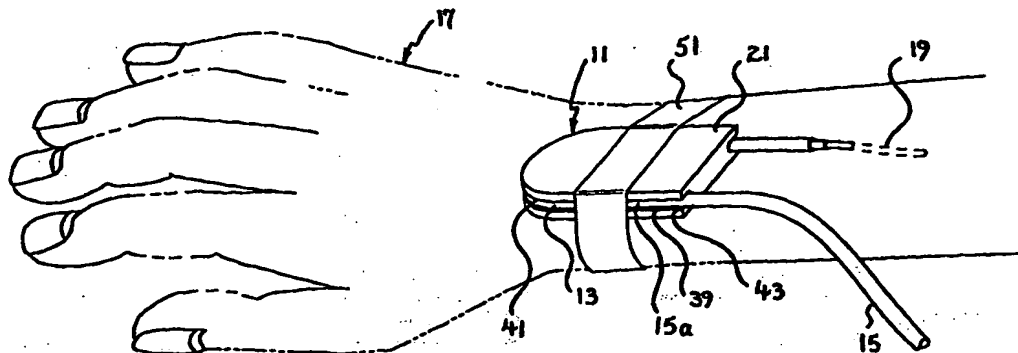




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/14, 5/32, 25/02	A1	(11) International Publication Number: WO 99/56802 (43) International Publication Date: 11 November 1999 (11.11.99)
(21) International Application Number: PCT/AU99/00332 (22) International Filing Date: 5 May 1999 (05.05.99) (30) Priority Data: PP 3329 5 May 1998 (05.05.98) AU (71) Applicant (for all designated States except US): MEDICAL MODULES PTY. LTD. [AU/AU]; Level 2, 52 Kings Park Road, West Perth, Perth, W.A. 6000 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): ROGERS, Julian, David [AU/AU]; 18 Grundy Way, Thornlie, Perth, W.A. 6108 (AU). TAYLOR, Anthony, Theophilus [AU/AU]; 2031 Albany Highway, Maddington, Perth, W.A. 6109 (AU). CHARTERS, John, Dumergue [AU/AU]; 8 Sayer Street, Midland, Perth, W.A. 6056 (AU). (74) Agent: WRAY & ASSOCIATES; 239 Adelaide Terrace, Perth, W.A. 6000 (AU).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: SAFETY LOOP SUPPORT DEVICE**(57) Abstract**

A device (11) for supporting a safety loop (13) in tubing (15) to be used for delivery of an intravenous fluid to a patient (17). The device (11) comprises a body (21) defining a guide path (39) which receives and supports a section (15a) of the tubing (15) in a curved arrangement thereby to create the safety loop in the tubing. The device (11) is adapted to be releasably attached to the body of the patient (17) by means such as strapping with adhesive tapes (51).

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TITLE

"Safety Loop Support Device"

FIELD OF THE INVENTION

This invention relates to a device for supporting a loop formation in flexible
5 tubing.

The invention has been devised particularly, although not solely, as a device for supporting a safety loop in tubing connected to an infusion needle or a catheter for intravenous delivery of a fluid to a patient.

BACKGROUND OF THE INVENTION

10 With intravenous delivery of fluid to a patient using IV tubing to convey the fluid from a source to the delivery site in the patient, it is common to create a safety loop in the tubing and to attach the tubing in the vicinity of the safety loop to the patient. One way of creating the safety loop is to use a device known as a "J-loop". A J-loop is a fitting has the configuration of a safety loop and which is
15 incorporated into the IV tubing. The fitting incorporates screw connectors for detachable connection to the tubing. While J-loops are satisfactory in operation, they do have several deficiencies. One deficiency is that it is necessary to install the IV tubing in position in two sections, with the two sections being connected together by the J-loop. The procedure for attaching the tubing to the J-loop using
20 the screw connectors can also be cumbersome. A further deficiency relates to the need for the J-loop to be in a sterile condition at installation, and to remain in a sterile condition during use. The requirement for sterile conditions arises because fluid delivered by the IV tubing actually passes through the J-loop.

It is against this background, and the deficiencies associated therewith, that the
25 present invention has been developed.

SUMMARY OF THE INVENTION

The present invention provides a device for supporting a loop formation in flexible tubing, the device comprising a body defining a guide path which receives and supports a section of the tubing in a curved arrangement thereby to create the
5 loop formation in the tubing.

The guide path may present a surface against which said section of the tubing locates when received in the guide path.

The surface presented by the guide path is preferably a continuous surface.

The guide path may include a curved portion and a straight portion at one end of
10 the curved portion. Preferably, however, the guide path includes two straight portions, one at each end of the curved portion.

The guide path may comprise a channel which receives at said section of the tubing.

A retaining means may be provided for releasably retaining said section of the
15 tubing in the guide path.

The retaining means may extend entirely along the guide path or may be located at spaced apart locations along the guide path. In one arrangement, the retaining means may be located only at the two straight portions of the guide path and not at the curved portion.

20 Where the guide path comprises a channel, the retaining means may comprise the two longitudinal side walls of the channel between which the tubing is frictionally engaged.

The present invention further provides a device for supporting a safety loop in tubing to be used for delivery of an intravenous fluid to a patient, the device

comprising a body defining a guide path which receives and supports a section of the tubing in a curved arrangement thereby to create the safety loop in the tubing, wherein the device is adapted to be releasably attached to the body of the patient.

5

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be better understood by reference to the following description of several specific embodiments thereof as shown in the accompanying drawings in which:

10

Figure 1 is a schematic view illustrating a device according to a first embodiment in use to form a safety loop if IV tubing used for delivery of an intravenous fluid to a patient.

Figure 2 is a perspective view of the device according to the embodiment;

Figure 3 is a view similar to figure 2 with the exception that the IV tubing is shown in position to form the safety loop;

15

Figure 4 is a sectional view along the line 4-4 of figure 3;

Figure 5 is an end view of the device shown in figure 2;

Figure 6 is an end view of a device according to a second embodiment;

Figure 7 is an end view of a device according to a third embodiment;

Figure 8 is an end view of a device according to a fourth embodiment;

20

Figure 9 is a perspective view of a device according to a fifth embodiment;

Figure 10 is a perspective view of a device according to a sixth embodiment;

Figure 11 is a perspective view of a device according to a seventh embodiment;

Figure 12 is a perspective view from the underside of the device shown in figure 11;

5 Figure 13 is a perspective view of a device according to an eighth embodiment;

Figure 14 is a side view of the device shown in figure 13;

Figure 15 is a perspective view of a device according to a ninth embodiment;

10 Figure 16 is a perspective view of a device according to a tenth embodiment shown in a condition in which it is partly fitted onto IV tubing to form a safety loop therein;

Figure 17 is a view of the device of figure 16 showing the device positioned on the IV tubing to form the safety loop; and

15 Figure 18 is a perspective view of a device according to an eleventh embodiment.

BEST MODE(S) FOR CARRYING OUT THE INVENTION

Referring to figures 1 to 5 of the accompanying drawings, there is shown a device 11 according to the first embodiment for supporting a safety loop 13 in IV tubing 15 for delivery of an intravenous fluid to a patient 17 by way of a catheterisation procedure utilising a conventional catheter 19 to which one end of the tubing 15 is connected. The other end of the tubing 15 is connected to a conventional fluid supply container.

The device 11 comprises a body 21 having an upper wall 23, a lower wall 25 and a side wall 27 extending between the two walls 23, 25.

The side wall 27 includes two straight sections 31, 32 and a curved section 33 between the two straight sections. The side wall 27 further includes an end section 35 which also extends between the two straight sections but which is opposite to the curved section 33.

The body 21 defines a guide path 39 for receiving and supporting a section 15a of the tubing 15 in a loop formation 41. The loop formation 41 provides the safety loop 13 in the IV tubing 15.

10 In this embodiment, the guide path 39 is defined by a channel 43 extending along the two straight sections 31, 32 and the curved section 33, and opening onto the end section 35, as best seen in figure 2 of the drawings. The channel 43 has a pair of opposed side walls 45 and an inner wall 47. The inner wall 47 of the channel 43 provides a continuous surface against which the section 15a of the tubing 15 which provides the loop formation 41 can locate when received and supported within the channel, as best seen in figure 4. The continuous surface defined by the inner wall 47 controls the curvature of the loop formation 41 so as to ensure that the curvature is not so tight as to form a kink or other restriction in the tubing 15. The spacing between the side walls 45 of the channel 43 is marginally smaller than the external diameter of the tubing 15 such that the tubing can be received within the channel in a friction fit with the side walls, thereby frictionally retaining the tubing 15 is frictionally retained within the channel 43 and so maintaining the loop formation 41 in the tubing.

25 Use of the device 11 creates the safety loop 13 within the IV tubing 15, as previously explained. The body 20 can then be attached to the patient 17 in any suitable fashion. In this embodiment, the body 20 is attached to the patient 17 by strapping it to the patient utilising adhesive tape 51, as show in figure 1.

- The embodiment provides a simple, yet highly effective, arrangement for forming the safety loop 13 in IV tubing 15 and then securing the IV tubing to the patient 17 in the manner required. The safety loop 13 is created merely by fitting the device 11 onto the tubing 15 at a location where the safety loop is required. This
- 5 can be done by simply winding the tubing 15 about the device 11 so as to insert the section 15a of the tubing into the channel 43. Once the safety loop 13 has been formed and the IV tubing 15 secured to the patient 17 by way of the device 11, the catheter 19 can be connected to the appropriate end of the tubing and the other end of the tubing connected to the fluid supply.
- 10 In the first embodiment, the channel 43 has an inner wall 47 which is curved to conform to the curvature of the IV tubing 15. It should however, be appreciated that the channel may be of any other suitable cross-section. Examples of other suitable cross-sectional configurations of the channel are illustrated in the embodiments shown in figures 6, 7, and 8 of the accompanying drawings.
- 15 In the embodiment shown in figure 6, the channel 43 has a generally rectangular cross-sections such that the inner wall 47 is flat.

The embodiment shown in figure 7 is somewhat similar to the embodiment shown in figure 5, with the exception that one side wall 45 of the channel 43 has a ramp formation 49 adjacent the outer end thereof for guiding the tubing 15 into

20 the channel 43.

The embodiment shown in figure 8 is also similar to the first embodiment in the sense that the guide path 39 for the tubing 15 is defined by a channel 43. In this embodiment, however, each side wall 45 has a ramp 51 adjacent the outer end thereof for assisting entry of the tubing into the channel. Furthermore, in this

25 embodiment, the retaining means for retaining the IV tubing 15 in position within the channel does not utilise frictional engagement (as was the case with the earlier embodiments) but rather comprises a retaining structure 52. The retaining structure 52 defines a gap 53 through which the tubing can be squeezed to gain access to a cavity 55 which is defined within the channel 43 and in which the

tubing is accommodated. The gap 53 is of a size marginally smaller than the external diameter of the tubing 15. The retaining structure 52 comprises two projections 57 on the opposed side walls 45 of the channel.

Referring now to figure 9 of the drawings, there is shown a device 11 somewhat similar to the earlier embodiments, with the exception that the body 21 incorporates a recess 61 which removes at least part of the straight section 31 in the side wall 27 of the body. Consequently, the end of the channel 43 associated with straight section 32 extends beyond the end of the channel associated with straight section 31.

10 The presence of the recess 61 in effect results in formation of a projection 63 on the body 21.

In use of the device 11 accordingly to this embodiment, the body 21 is strapped or otherwise secured to the patient about the projection 63. This can be useful in cases when there is a confined or limited area on the body of the patient to attach
15 the device 11.

Referring now to figure 10 of the drawings, there is shown a device 11 in which the body 21 comprises a tubular structure 65 configured in a U-shape, and a cross-piece 67 extending between the arms of the U-shape. The tubular structure 65 provides a guide path 39, the curvature of which corresponds to the
20 desired curvature of the safety loop to be formed in IV tubing by the device.

A longitudinal slit 69 is provided in the tubular structure 65 to define a gap through which the IV tubing can be inserted laterally into the tubular structure. The tubular structure 65 with the slit 69 therein in effect provides a channel in the device for receiving the IV tubing. The width of the slit 69 is marginally smaller
25 than the external diameter of the tubing, such that the tubing must be squeezed through the slit. This arrangement provides the means by which the tubing is retained in the tubular structure 65.

Referring now to figures 11 and 12 of the drawings, the device 11 according to this embodiment comprises a body 21 having an upper wall 23, a lower wall 25, and a side wall 27 including an end section 35. The guide path 39 comprises a channel 71 formed in the lower wall 25 of the body, with the ends of the channel 5 71 opening onto the end section 35. As with the first embodiment, the IV tubing 15 is received in the channel 71 and retained therein by way of frictional engagement with the side walls 73 of the channel 61.

In the embodiments which have previously been described and illustrated, the guide path 39 has been defined by a channel, with the longitudinal side walls of 10 the channel defining retaining means for releasably retaining the IV tubing 15 in the channel. It should be appreciated, however, that the retaining means can be formed separately of the side walls of the channel. Figures 13 and 14 of the drawings illustrates an embodiment which utilises such an arrangement.

The device 21 shown in figures 13 and 14 has retaining means 75 comprising a 15 first set of projections 77 located in a spaced apart relationship and a second set of projections 79 located in a spaced apart relationship. The projections 77, 79 define a guide path 34 therebetween. The projections 77 are on longitudinal on one side of the guide path and the projectors 79 are on the other longitudinal side of the guide path. The projections adjacent one longitudinal side are in an offset 20 relationship with the projections 79 adjacent the other longitudinal side. With this arrangement, the tubing can be weaved between the projections 79 in the first and second sets 77, 79 and then moved laterally into the guide path. The interleaved relationship between the projections 77, 79 serves to retain the tubing in position within the guide path 34.

25 Referring now to figure 15 of the drawings, there is shown a further embodiment of the device 11 comprises a body 21 in the form of a base 81. A plurality of clips 83 are mounted on the base 81. The clips 83 are adapted to releasably engage the IV tubing. The clips 83 are positioned in spaced apart relationship in a somewhat U-shape configuration, as shown in the drawings. With this

configuration, the clips 83 serve to configure the section of the IV tubing retained by the clips into a loop formation thereby to provide the safety loop. In this way, the clips 83 cooperate with each other to define both a guide path for the IV tubing and a retaining means for releasably retaining the safety loop in the guide
5 path.

Referring now to figures 16 and 17, the device 11 according to this embodiment comprises a body 21 which includes a first portion 91 and a second portion 92. The first portion 91 comprises a base 93 having a side wall 95. The side wall 95 includes two straight side sections 96 and a curved section 97 between the two
10 straight sections 96. The side wall 95 has an opening 98 in opposed relation to the curved section 97.

The base 93 supports a mounting post 99 in the form of a spindle.

The second portion 92 comprises a disc structure 101 having a channel 103 formed in the outer periphery thereof to receive a section 15a of the IV tubing 15 to form a loop formation 41. The channel 103 defines a guide path for the section
15 15a of the tubing.

The second portion 92 has a central aperture 105.

The second portion 92 can be mounted on the first portion 91 with the disc 101 received within the space defined by the side wall 95, and the spindle 99
20 received within the opening 105, as shown in figure 17 of the drawings. In this way, the side wall 95 serves to retain the section 15a of the IV tubing 15 in the guide path defined by the channel 103.

With this arrangement, it is a simple matter to remove the disc 101 from the first portion 91 to insert, and remove, the IV tubing as necessary.

25 Referring now to figure 18 of the drawings, there is shown a device 11 which comprises a body 21 having a channel 111 defining a guide path for forming a

loop formation 41 in the IV tubing 15 to create the safety loop 13. The device 11 includes retaining means 113 for releasably retaining the section 15a of the tubing in position with respect to the guide path thereby to maintain the loop formation 41. The retaining means 113 comprises two barriers 115 each
5 mounted on a base 117 forming part of the body 21. The barriers 115 are positioned each adjacent, but in spaced relation to, a respective end of the channel 111 such that the tubing can be manoeuvred around the barriers 115. The tubing can be so positioned that the barriers are located on the outer side of the tubing with respect to the body (as shown in the drawing) thereby to retain the
10 tubing in the guide path. To remove the device 11 from the tubing 15 when the safety loop is no longer required, it is a simple matter to manoeuvre the tubing 15 over each barrier 115 so as to allow removal of the tubing section 15a from the guide path defined by the channel 111.

From the foregoing, it is evident that the present invention provides a simple yet
15 highly effective device for establishing a safety loop in IV tubing. The device also provides a simple way for securing the tubing in the vicinity of the safety loop to a patient.

In the embodiments which have described, the IV tubing is attached to the body of the patient in the vicinity of the safety loop by strapping the body 21 to the
20 patient, such as by way of adhesive strapping as shown in figure 1 of the drawings. It should, however, be appreciated that the body 21 can be attached to the patient in any other suitable fashion such as by using hook and loop fastening attachments or other adhesive structures.

It should also be appreciated that the scope of the invention is not limited to the
25 scope of the various embodiments which have been described.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS

1. A device for supporting a loop formation in flexible tubing, the device comprising a body defining a guide path which receives and supports a section of the tubing in a curved arrangement thereby to create the loop formation of the tubing.
5
2. A device according to claim 1, wherein the guide path presents a surface against which said section of the tubing locates when received in the guide path.
3. A device according to claim 2 wherein the surface presented by the guide path is a continuous surface.
10
4. A device according to any one of the preceding claim wherein the guide path includes a curved portion and a straight portion at one end of the curved portion.
5. A device according to claim 4 wherein the guide path includes a straight portion at each end of the curved portion.
15
6. A device according to any one of the preceding claims wherein the guide path comprises a channel which receives said section of the tubing.
7. A device according to any one of the preceding claims further comprising retaining means for releasably retaining said section of the tubing.
- 20 8. A device according to claim 7 wherein the retaining means extends entirely along the guide path.
9. A device according to any one of claims 1 to 7, wherein the retaining means is positioned at spaced apart locations along the guide path.

10. A device according to claim 7 wherein the guide path comprises a channel and wherein the retaining means comprises the two longitudinal side walls of the channel between which the tubing can be frictionally engaged.
11. A device according to claim 7, 8 or 9 wherein the retaining means comprises
5 a retaining structure for releasably retaining a tubing in the guide path.
12. A device according to claim 11 wherein the retaining structure comprises a means defining a gap through which the tubing can be squeezed.
13. A device according to claim 11 wherein the retaining structure comprises a barrier means for releasably retaining the tubing in the guide path.
- 10 14. A device according to claim 13 wherein the barrier means comprises a fixed barrier about which the tubing can be manoeuvred for insertion into and removal from the guide path.
- 15 15. A device for supporting a safety loop in tubing to be used for delivery of an intravenous fluid to a patient, the device comprising a body defining a guide path which receives and supports a section of the tubing in a curved arrangement thereby to create the safety loop in the tubing, wherein the device is adapted to be releasably attached to the body of the patient.
16. A device substantially as herein described with reference to the accompanying drawings.

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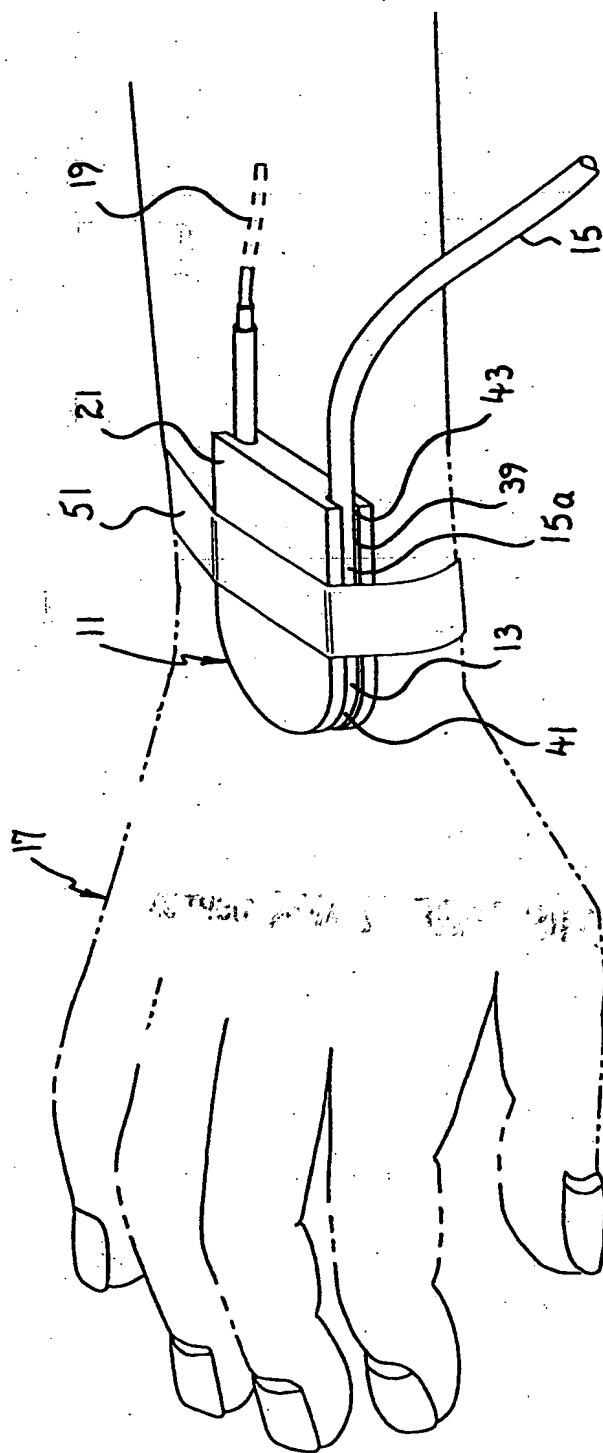


Fig. 1

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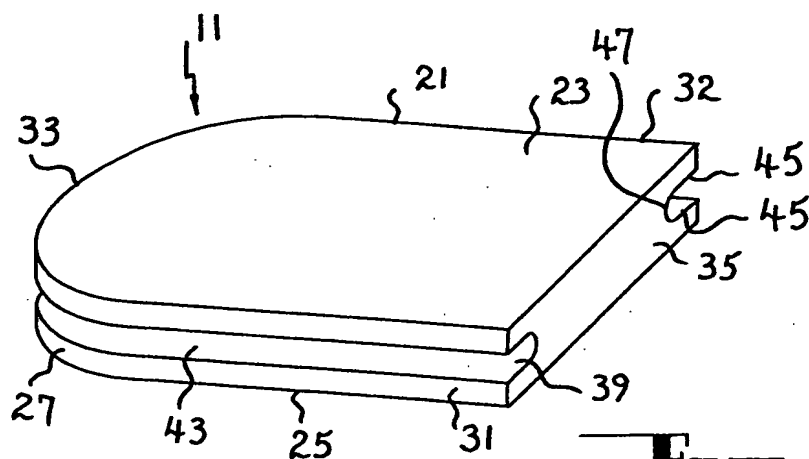


Fig. 2

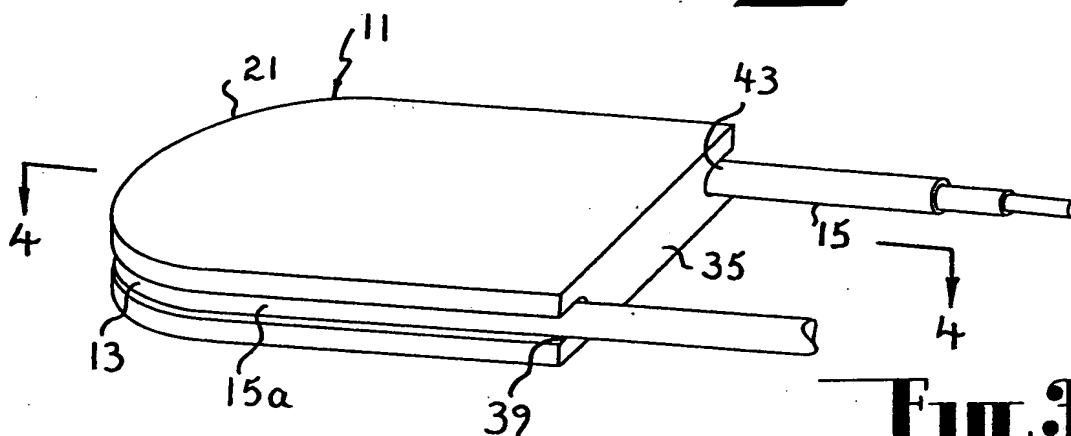


Fig. 3

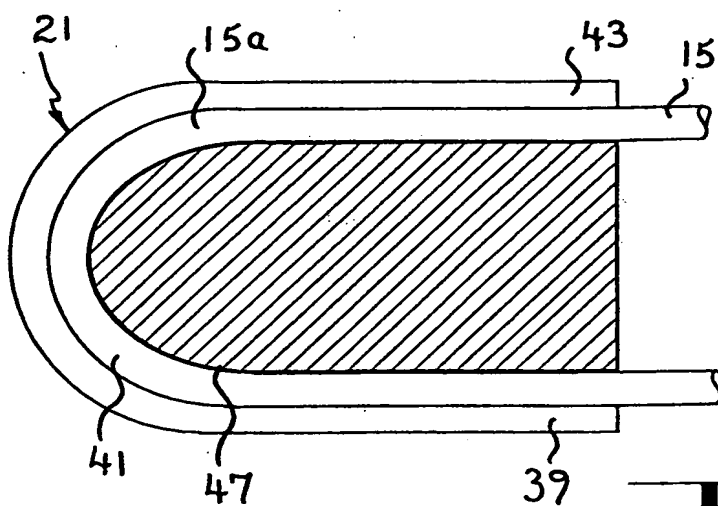
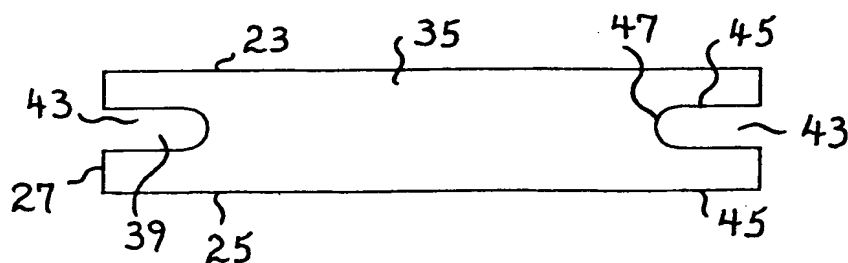
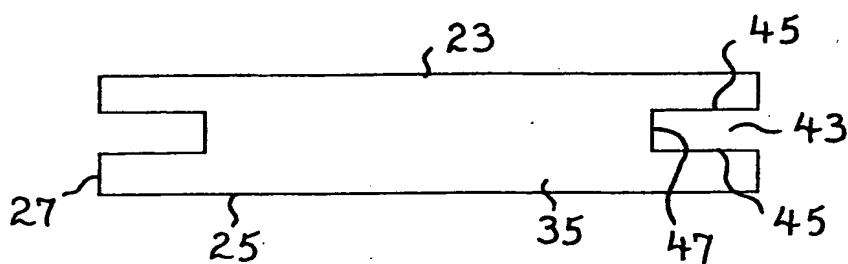
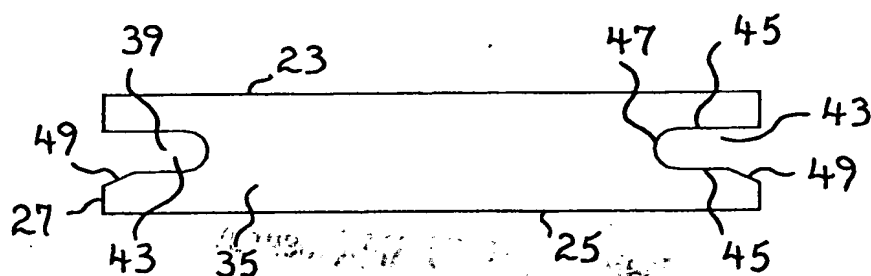
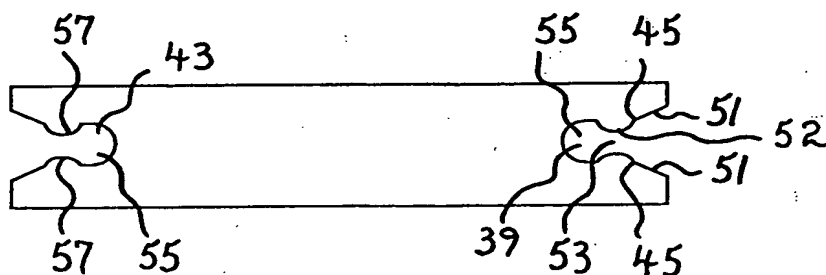


Fig. 4

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**Fig. 5,****Fig. 6,****Fig. 7,****Fig. 8,**

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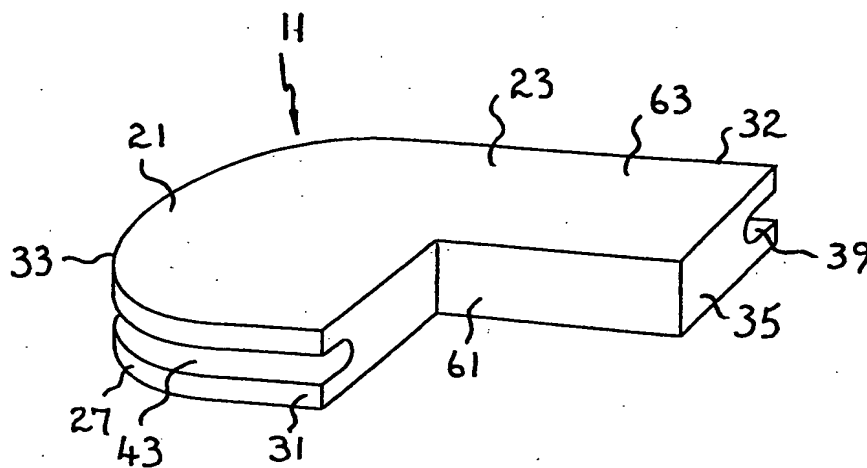


Fig. 9.

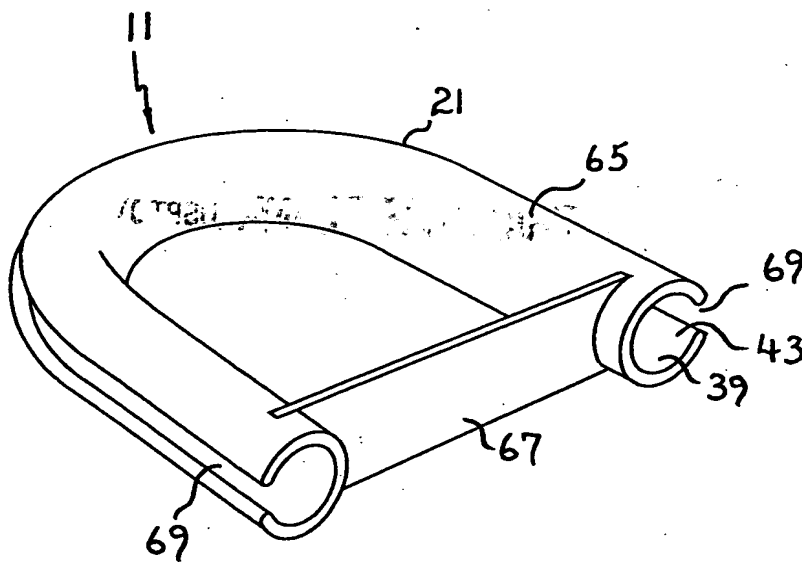


Fig. 10.

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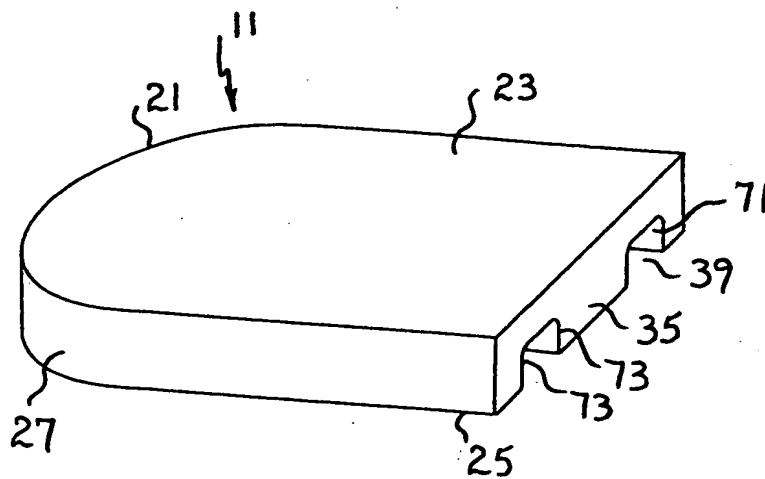


Fig. 11.

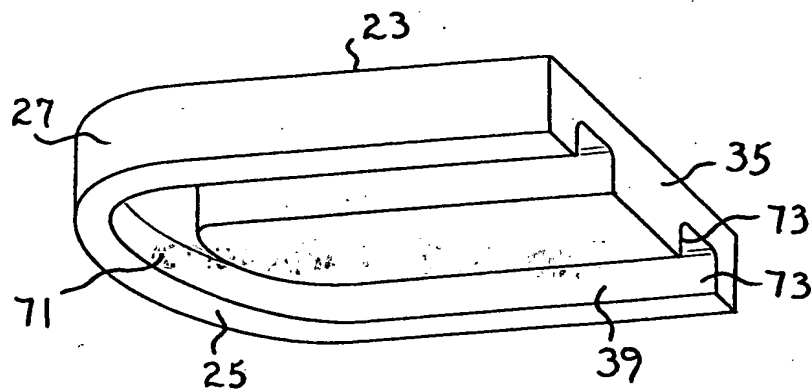
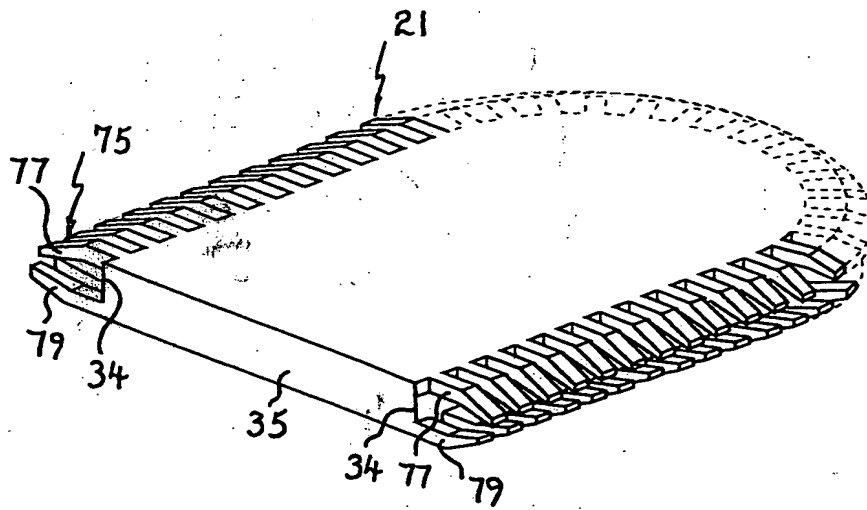
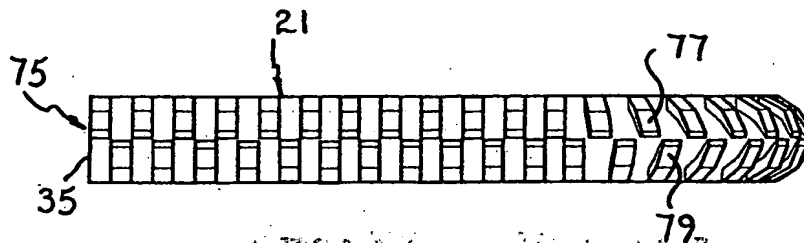


Fig. 12.

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**Fig. 13.****Fig. 14.**

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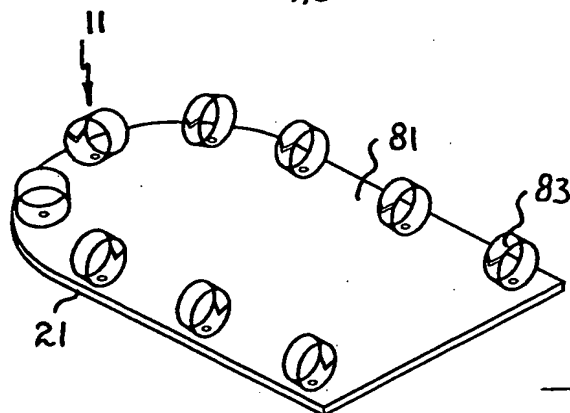


Fig. 15.

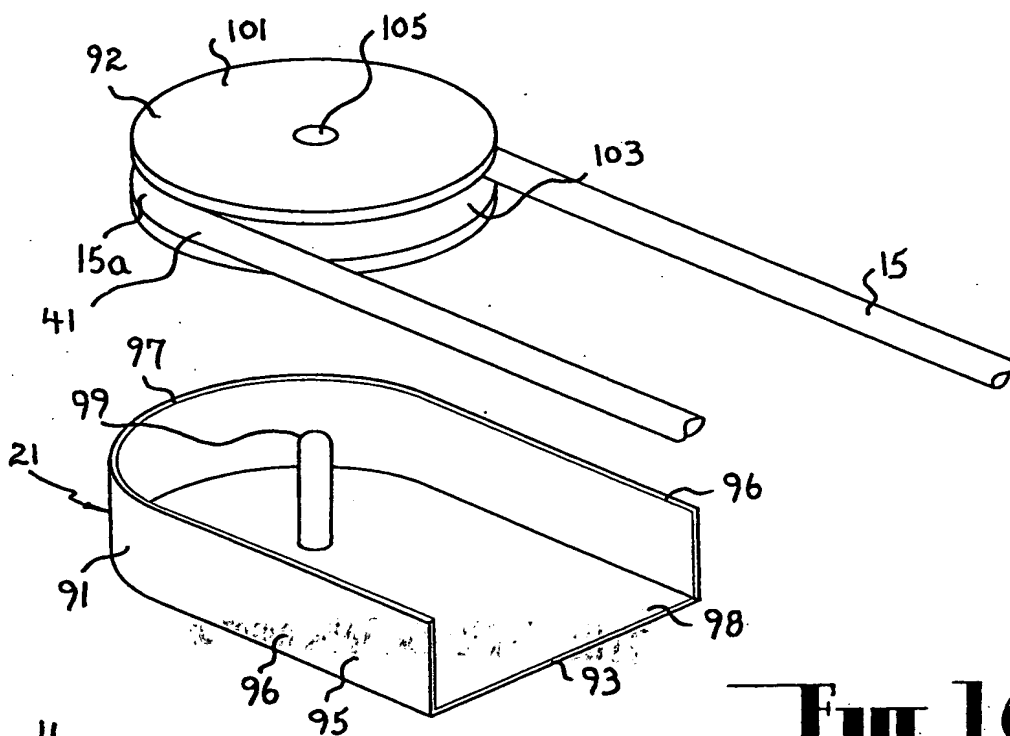


Fig. 16.

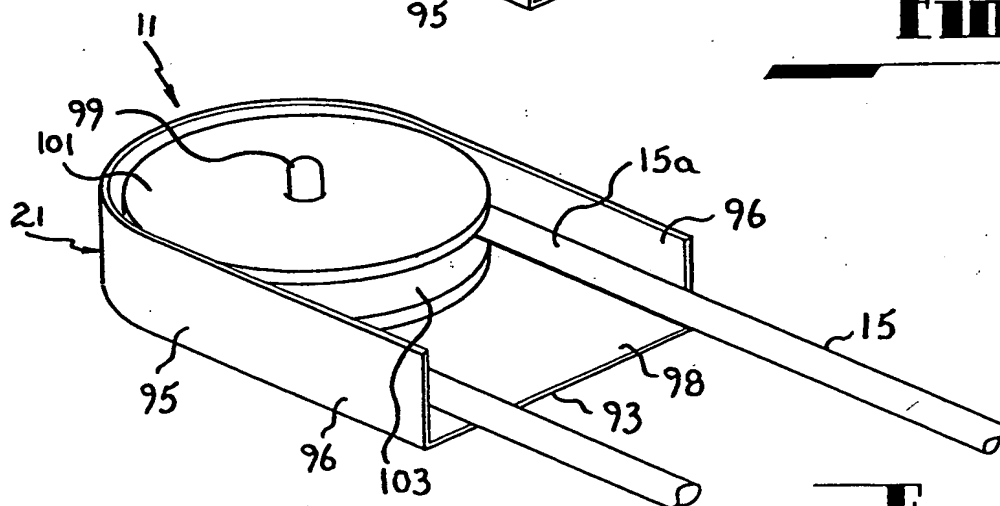


Fig. 17.

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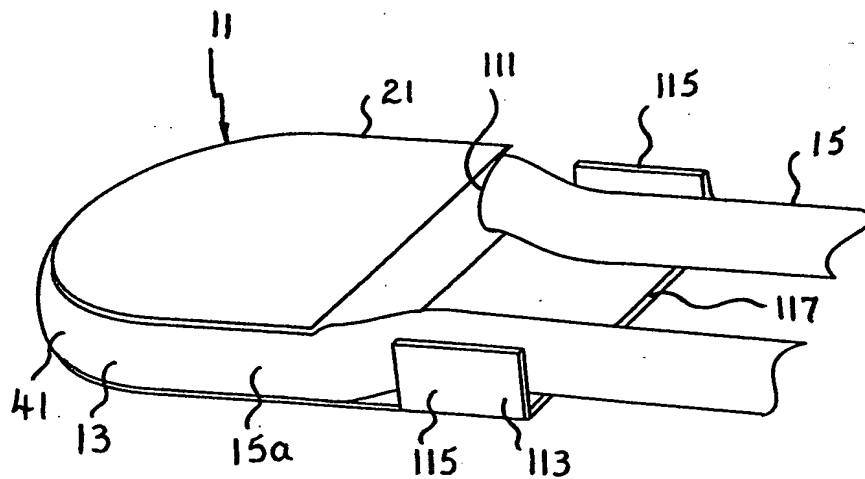


Fig. 18

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00332

A. CLASSIFICATION OF SUBJECT MATTER		
Int Cl ⁶ : A61M 5/14, 5/32, 25/02		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC: A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DERWENT		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4976698 A (STOKLEY) 11 December 1990 Abstract; Figures	1-8, 10-11, 15
X	US 4397641 A (JACOBS) 9 August 1983 Abstract; Figures	1-3, 6-8, 10-11, 15
X	US 4316461 A (MARAIS et al.) 23 February 1982 Abstract; Figures; Column 2, lines 46-50	1, 4, 7, 9, 11-15
X	US 4484914 A (BROWN) 27 November 1984 Abstract; Figures	1, 4-5, 7, 9, 11, 13, 15
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Date of the actual completion of the international search 15 June 1999		Date of mailing of the international search report 06 JUL 1999
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer ROSEMARY LONGSTAFF Telephone No.: (02) 6283 2637

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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/EP 03/00569

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M39/08 A61M25/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M B65H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 406 042 A (MCPHEE CHARLES J) 27 September 1983 (1983-09-27) figures 1-6 abstract	1-22
A	--- EP 1 060 757 A (SEACREST TECHNOLOGY LTD) 20 December 2000 (2000-12-20) figures 1-9 abstract	1-22
A	--- US 4 662 873 A (LASH ROBERT ET AL) 5 May 1987 (1987-05-05) figures 1-6 abstract	1-22
A	--- US 4 606 735 A (WILDER JOSEPH R ET AL) 19 August 1986 (1986-08-19) abstract -----	1-22

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Date of the actual completion of the international search

24 November 2003

Date of mailing of the international search report

21 JAN. 2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 03/00569

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4406042	A	27-09-1983	NONE	
EP 1060757	A	20-12-2000	US 6405414 B1 EP 1060757 A1 IE 20000389 A1	18-06-2002 20-12-2000 27-12-2000
US 4662873	A	05-05-1987	NONE	
US 4606735	A	19-08-1986	NONE	

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